II. CONDUCTING THE ETS HOME VISIT ASSESSMENTS

A. Overview and Purpose of Home Visit Assessments

The ETS Home Visit assessments are conducted at the following assessment periods: baseline, 6-weeks postpartum, and 6- and 12-months postpartum. The purpose of the home visit assessments is to evaluate the:

- ETS program delivered to participants assigned to the ETS intervention group; and
- Safety program delivered to participants assigned to the attention-control group.

During the home visit assessments, you will conduct activities to assess both components of the study, i.e., maternal, infant, and household ETS exposure, maternal knowledge of household safety precautions, and implementation of household safety measures. Each of these activities will be conducted among all participants regardless of their cohort assignment and treatment group.

Each assessment period (e.g., the baseline home visit assessment) consists of two homes visits (Home Visits A and B) which are scheduled one week apart. Therefore, you will conduct a total of eight home visits with each participant. **Be aware that the baseline home visits must be conducted before the mother delivers; therefore, it is important that these two visits are conducted as quickly as possible following recruitment of the study participant**. Information regarding scheduling and contacting participants to conduct the home visits is included in ***Sections II.E.1*** and ***II.E.2***.

Tables II-1 and ***II-2*** below list all home visit assessment activities that will be conducted for Home Visits A and B, respectively, the timing of each activity (i.e., baseline, postpartum or both), and the purpose of the activity (i.e., assessment of the ETS or safety component of the study). More detailed descriptions of each activity are included in ***Sections II.B*** and ***II.C*** below.

Table II-1: Home Visit Assessment Activities for Home Visit A

Assessment Activities to be Conducted	Timing	Purpose
1. Introductions and obtain consent using Home Visit Safety Observation Consent Form	Baseline/PP	Safety assessment
2. Draw Household Map and administer Nicotine Monitor Placement and Safety Observation Determination Form	Baseline/PP	ETS and safety assessment
3. Placement of ETS nicotine monitors and explain purpose/use	Baseline/PP	ETS assessment
4. Distribute 7-Day Activity Calendar and explain purpose/use	PP only	ETS assessment
5. Administer Tymchuk's Home Inventory of Dangers & Safety Precautions	Baseline/PP	Safety assessment
6. Complete Home Safety Observation (adapted from Home Accident Prevention Inventory -- Revised (HAPI-R) by Tertinger, Greene, and Lutzker, 1984, and revised by Mandel et al., 1998)	Baseline/PP	Safety assessment

Table II-2: Home Visit Assessment Activities for Home Visit B		
Assessment Activities to be Conducted	**Timing**	**Purpose**
1. Introductions and address any questions	Baseline/PP	N/A
2. Collect infant urine sample	PP only	ETS assessment
3. Administer smoking and ETS questions from 7-Day Activity Diary	PP only	ETS assessment
4. Collect maternal saliva sample	Baseline/PP	ETS assessment
5. Ask mother to complete Tobacco Smoke Exposure Questionnaire (self-administered)	Baseline/PP	ETS assessment
6. Collect nicotine monitor (leave "long-term" monitor)	Baseline/PP	ETS assessment

B. Components of Home Visit A

The manner in which you present yourself when you visit the mother at her home is critical for obtaining her cooperation for the visit. It is important that you immediately introduce yourself, show the mother your DC-STEP: Healthy Infants and Mothers Program badge, and thank her for setting aside the time for the visit. Next, you will explain what you will be doing during the home visit. Be sure to address any questions or concerns the participant may have. If the participant is concerned about the length of time for the visit, tell her you will try to get through as much as possible, and if necessary, you can finish the remaining activities during the second home visit. Note, however, that you must at least conduct the following activities during the first home visit (1) drawing of Household Map and administration of the Nicotine Monitor Placement and Safety Observation Determination Form and (2) place the nicotine monitors in the home. For the postpartum assessments, you must also (1) explain and provide a copy of the 7-Day Activity Calendar and (2) provide the mother with instructions and materials necessary for the infant urine collection during the first visit. All other activities, such as the Tymchuk Home Inventory and Home Safety Observation can be completed, if necessary, during Home Visit B. If for some reason, you are not able to conduct the key activities listed above, you must re-schedule Home Visit A as soon as possible, preferably sometime during the same week.

1. Obtain Consent for Home Observation

Begin the home visit by asking the participant to read and sign the *Home Visit Observation Consent Form* as discussed in ***Section II.G*** below.

2. Draw Household Map and Administer Nicotine Monitor Placement and Safety Observation Determination Form

Once you have reviewed the *Home Observation Consent Form*, you will need to (1) draw a map of the household and (2) administer the *Nicotine Monitor Placement and Safety Observation Determination Form*. Both activities are designed to capture information to determine the location of the nicotine monitor placement and to assist with the home safety observation. Further information regarding the drawing of the household map and administration of the *Nicotine Monitor Placement and Safety Observation Determination Form* is included in ***Chapter III***.

3. Explanation and Placement of Nicotine Monitors

After completing the *Nicotine Monitor Placement and Safety Observation Determination Form* and updating the map to indicate where you are placing the monitors, you will then place the monitors in the specified locations. For each home visit assessment, you must document the placement and collection of the nicotine monitors using the *Nicotine Monitor Collection Form*. Detailed instructions for placing the monitors in the home, completing the *Nicotine Monitor Collection Form*, and shipping the monitors to the laboratory at Johns Hopkins University for testing are included in ***Chapter IV***.

4. Explanation and Distribution of 7-Day Activity Calendar (Postpartum Home Visits Only)

For the post-partum home visit, we will also assess the baby's exposure to tobacco smoke during the past seven days based on the mother's self-report. To facilitate this interviewing process, each mother will be asked to complete a *7-Day Activity Calendar*. You will provide the mother with a copy of the *7-Day Activity Calendar* during Home Visit A, and you will ask her to document her activities on a daily basis for the next seven days. When you return for Home Visit B, the mother will refer to the *7-Day Activity Calendar* as you ask her specific questions to ascertain the amount of cigarettes smoked around her and her baby in various situations (e.g., in the home, away from home, etc.) An example of a completed Calendar, the questions for assessing the mother's and infant's exposure to tobacco smoke, and specific instructions for completing both forms are included in ***Chapter V***.

5. Administering Tymchuk's Home Inventory of Dangers & Safety Precautions

As part of the procedures for assessing the safety and development intervention given to the participants assigned to the attention-control group, ALL participants, regardless of treatment group assignment, will be asked to complete *Tymchuck's Home Inventory of Dangers and Safety Precautions*. This activity requires the participant to look at pictures of four to five different areas of a household to identify potential safety hazards and precautions to avoid such dangers. Copies of the household pictures, the *Tymchuck Home Inventory Data Form*, and detailed instructions for completing the form are included in ***Chapter VI***.

6. Conducting the Home Observation Safety Assessment (adapted from the HAPI-R)

Following the administration of the Tymchuck Home Inventory, you will then conduct the *Home Observation Safety Assessment* (adapted from the HAPI-R). To conduct the *Home Safety Observation Assessment*, you will need to observe up to five possible rooms in the house. Keep in mind that you must have the mother's consent to conduct the home observation. A copy of the *Home Safety Observation Data Form* and detailed instructions for completing the form are included in ***Chapter VII***.

7. Asking the Mother's Assistance for Infant Urine Collection (Postpartum Visits Only)

As noted above, for the postpartum assessments, you will need to collect an infant urine sample during Home Visit B. To collect urine from the infant during Home Visit B, you will need to ask the mother during Home Visit A to assist you with this task. You will provide the mother with two pairs of diaper liners, and you will ask her to use the diaper liners to collect two urine samples from the baby's diaper on the day that you plan to conduct Home Visit B. The instructions for the mother, procedures for extracting the urine samples from the diaper liners, and shipping them to the GW lab are included in ***Chapter VIII***.

8. Concluding Home Visit A

Once you have completed all Home Visit A activities, you may conclude the visit by (1) thanking the mother for her time; (2) scheduling the date and time for Home Visit B (seven days from Home Visit A) and giving a brief overview of Home Visit B activities; (3) asking the mother if she has any questions or concerns regarding today's visit or the next visit; and (4) documenting the completion of Home Visit A activities, the appointment time for Home Visit B, and updating any contact information in the Home Visit Activities Booklet. Instructions for initiating and completing the Home Visit Activities Booklet are included in ***Sections E.3*** and ***F.2*** below.

C. Components of Home Visit B

1. Introductions/Address Any Questions

When you first arrive to the home, re-introduce yourself as necessary and ask the mother if she has any questions before you begin the home visit activities. You may remind her again that the visit should be shorter than the previous visit, and thank her once again for her cooperation. (During the confirmation call, you will have given her an overview of the home visit activities, so she should already be familiar with what you are planning to do during the visit.)

2. Collect Infant Urine Samples (Postpartum Home Visits Only)

After arriving to the participant's home and re-acquainting yourself with the mother, you should immediately determine whether or not the mother has collected any of the baby's diapers using the diaper liners. Procedures for (a) collecting the diaper samples, (b) what to do if the mother has not collected the diaper samples or if the samples are contaminated with feces or baby powder/ointment, (c) extracting urine from the diapers, and (d) sending the samples to the GW laboratory are included in ***Chapter VIII*** below.

3. Administer 7-Day Activity Diary – Smoking Questions (Postpartum Home Visits Only)

As discussed above, during the post-partum visits, we will also assess the baby's exposure to tobacco smoke during the past seven days based on the mother's self-report. To facilitate this interviewing process, during Home Visit A, each mother will be asked to complete a 7-Day Activity Calendar. When you return for Home Visit B, the mother will refer to the 7-Day Activity Calendar as you ask her specific questions to ascertain the amount of cigarettes smoked around her and her baby in various situations (e.g., in the home, away from home, etc.) An example of a completed Calendar, the questions for assessing the mother's and infant's exposure to tobacco smoke, and specific instructions for completing both forms are included in ***Chapter V***.

4. Collect Maternal Saliva

We will also assess the mother's own exposure to tobacco smoke by asking her to provide a saliva sample. The saliva collection procedure is simple and non-invasive; more detailed information regarding the saliva collection process is included in ***Chapter VIII***.

5. Ask Mother to Complete Tobacco Smoke Exposure Questionnaire (self-administered)

Each time you collect a saliva sample from the mother, you will need to ask her to complete the Tobacco Smoke Exposure Questionnaire. A copy of this questionnaire and instructions for administering it are included in ***Chapter VIII***.

6. Collect Nicotine Monitors (Leave Long-Term Monitor)

Prior to leaving the home, be sure to collect the appropriate nicotine monitors. One monitor (the "long-term" monitor) will be left in the home for the duration of the study. Remind the mother that it's very important that no one in household touches or moves the monitor. More detailed instructions for collecting the monitors, documenting the collection process, and shipping the monitors to the laboratory at Johns Hopkins are included in ***Chapter IV***.

7. Conclude Home Visit B

Once you have completed all Home Visit B activities, be sure to thank the mother for her time and provide her with her incentive payment (if she has completed the telephone interview). If she has not completed the telephone interview, ask her to call the interviewers at CNMC (if possible while you are still there) to arrange a date/time to conduct the interview and inform her that once she completes the interview, she can then pick up her incentive payment at the clinic. Information regarding the distribution of the incentive payments is included in ***Section F.1*** below. You should also inform the mother when you plan to visit her again (e.g., 6-weeks after the baby is born or when the baby is 6 or 12 months old) and either schedule a tentative date for that visit or obtain information regarding best times to conduct that visit. Tell her that you will

call her about two weeks before the next visit to arrange/confirm the exact date/time. Be sure to document the completion of all activities and any scheduling information on the Home Visit Activities Booklet as described in ***Sections E.3*** and ***F.2*** below.

D. List of Forms and Materials for Home Visit Assessments

As a Home Visitor for the ETS Study, you will be responsible for preparing, organizing, and bring all necessary forms and materials with you when you conduct the home visit assessments. A summary of all forms and materials needed for each home visit is included in ***Table II-3*** below.

Table II-3: List of Forms and Materials Necessary for Home Visits

Home Visit A – Baseline	**Home Visit B –Baseline**
1. Home Visit Activities Booklet 2. Home Safety Observation Consent Form 3. Household Map Forms & Materials: (a) Household Map Drawing/Data Form, (b) Nicotine Monitor Placement and Safety Observation Determination Form (baseline version), (c) laser measuring tape, (d) highlighter, (e) pen(s), (f) pencil(s) with lead (0.9mm), (g) Sharpie pen, (h) correction pen, (i) calculator, (j) clear clipboard, (k) bag to carry all materials. 4. Nicotine Monitor Forms & Materials: (a) Nicotine Monitor Drop-off Form, (b) Sample Sheet, (c) monitors in urine cups (primary, duplicate, blank, long-term, and extra), (d) blank labels, (e) plastic surgical gloves (powder-free), (f) Ziplock plastic baggies, (g) masking tape, (h) string, (i) scissors, (j) ballpoint pen, (k) measuring tape, (l) calendar and/or Atomix clock/watch, and (m) extra batteries for clock/watch. 5. Tymchuk Home Inventory Forms & Materials: (a) Home Inventory of Dangers & Safety Precautions – Data Form and (b) laminated photos of household rooms (living room, kitchen, baby's bedroom, bathroom, stairs) 6. Home Safety Observation Forms and Materials (a) Data Form, (b) Scoring Instructions, (c) Poisonous Plant Summary, (d) measuring tape, (e) thermometer, (f) replacement battery, (g) extendable/retractable pole (e.g., golf ball retriever or paint roller), (h) flashlight, (i) empty toilet paper roll, (j) pen/pencil and clipboard 7. Portable refrigerator (if selected for blank monitoring)	1. Home Visit Activities Booklet 2. Nicotine Monitor Pick-Up and Drop-Off Form 3. Empty urine cups for monitors and red monitor caps (bottoms) 3. Tobacco Smoke Exposure Questionnaire 4. Saliva collection materials: (a) Salivette Citric Acid, (b) biohazard stickers, (c) Ziplock plastic baggies 5. Portable refrigerator 6. Decon Bacdown Gel

Home Visit A- <u>Additional</u> Materials for Postpartum Visits	**Home Visit B- <u>Additional</u> Materials for Postpartum Visits**
Items #1-7 above from baseline PLUS: 1. Nicotine Monitor Placement and Safety Observation Determination Form (Postpartum version) 2. 7-Day Activity Calendar 3. Urine collection materials for mother: (a) at least 4 diaper liners, (b) 2 lager Ziplock plastic baggies, and (c) 2 pairs of plastic gloves	Items #1-6 above from baseline PLUS: 1. 7-Day Activity Diary – Smoking Questions 2. Urine collection materials: (a) at least 4 diaper liners, (b) 2 large Ziplock plastic baggies, (c) 2 pairs of plastic gloves, (d) 1-2 urine cups, (e) biohazard stickers, and (f) 2-3 sterile syringes

E. Pre-Home Visit Activities

1. Contacting and Scheduling Participants for Home Visit A

At the beginning of each week (i.e., every Monday), you will need to generate the Home Visits Scheduled/To Be Scheduled Report from the Data Management System. This report includes a list of all participants who are in need of a home visit. The report indicates (1) the type of home visit needed (e.g., baseline, 6-week, etc.); (2) whether or not the home visit has already been scheduled, and if so, the date and time of the appointment; and (3) contact information for the participant so that you may confirm appointment times and/or schedule an appointment as needed. For an example of the Home Visits Scheduled/To Be Scheduled Report and steps for generating this report, refer to the ***DMS Manual of Operations***.

Once you have generated this report, you may use this report to confirm or scheduled appointments with participants. All participants with a scheduled appointment MUST be called the day before their appointment. If the appointment falls on a Monday, the participant MUST be called the Friday before the appointment. If a participant's name appears on this report and a visit has not been scheduled, begin calling the participant as soon as possible to schedule his/her appointment. This is especially critical for the baseline home visits, since these visits must be completed before she delivers her baby and are necessary for randomization.

When calling to schedule appointments, you will need to introduce yourself and explain the purpose of the home visits. This is especially important for the baseline assessment since this be the first time you are visiting the mother's home. An example script to use at baseline is included below:

Hello, my name is _____, and I am the Home Visitor for the DC-STEP: Healthy Infants and Mothers Programs. As you know, we will be conducting two home visits a week apart every few months; I would like to schedule the first of those visits. We will conduct another set of two home visits when your baby is 4-6 weeks old, and then again at 6 and 12 months of age.

The reason for our visits is to collect information that will help you to protect your baby from safety risks and exposure to environmental tobacco smoke. The information we collect today and at each subsequent visit will be shared with your Infant Health Advisor. Depending on

which intervention you were selected to receive, she will provide you with feedback and assistance in ways to reduce your baby's risk.

First, we will draw a map of the floor plan of your own house that shows the location and the size of rooms in your house. Then, I will ask you a few questions about which rooms you, other members of your family and your baby or other children spend the most time. This information will help us decide where the best place is to put the nicotine monitors, and which rooms are most important to focus on to reduce safety hazards.

Another area of interest during today's visit is home safety. Therefore, we would like to review a series of photographs showing the typical rooms in a house, and I will ask you to identify any hazards you think exist and how you might fix them.

After that, with your permission, we will walk through your home together looking at each room where the baby is most likely to spend time "from the child's-eye level" to find all of the hazards that infants and children are likely to find. We will only look in the rooms or areas where you give us permission to go. You can tell me which areas and places are "off-limits" before we begin.

This information will be helpful to you and the Infant Health Advisor, since it she will use it to help you identify ways to make your home safer for your new baby and any other children you might have.

This visit should last about 1-2 hours. What date and time within the next week would be best for you?

When calling to confirm appointments, be sure to verify the exact date and time of the visit and emphasize that we will need to be at the home for 1-2 hours.

2. Confirming Appointment Date/Time for Home Visit B

The day before Home Visit B, you will need to call the mother to confirm the date and time of the appointment. During this call, you should ask her (1) if there has been any problems with the nicotine monitors and remind her to leave them alone and (2) if she has any questions about the upcoming visit. When explaining the purpose of Home Visit B, be sure to emphasize the following key points: (a) Home Visit B will be much shorter; (b) you will collect all but one of the nicotine monitors; and (c) you will collect a saliva sample from the mother and ask her to complete a brief questionnaire about her exposure to cigarette smoke during the past seven days. For *postpartum visits only*, you will also need to (1) ask the mother if she has been completing the 7-Day Activity Calendar, and if not, ask her to fill it out prior to the visit; and (2) inform her that you will need to collect two of the baby's diapers (using the diaper liners) for the infant urine specimen collection so it's important that she use the diaper liners in her baby's diapers before you arrive for Home Visit B. Specifically, she should plan to use the diaper liners in two separate diapers that are placed on the baby about 4-6 hours before you arrive for the visit or first

thing in the morning if you have scheduled a morning home visit. Remind her that it is very important that the diapers are still "wet" when you arrive for the visit.

3. Initiating the Home Visit Activities Booklet

Prior to calling the mother to schedule the baseline home visits, you will need to initiate a *Home Visit Activity Booklet* by completing Section A of the booklet. A copy of the *Home Visit Activities Booklet* is included at the end of this chapter. Section A (mother's name, baby's name, and telephone numbers) can be completed using information from either the *Home Visits Scheduled/To Be Scheduled Report* or the *Individual Activities Report* in the DMS. Instructions for accessing this information from the DMS are included in ***DMS Manual of Operations***. Once you initiate the *Home Visit Activity Booklet*, you will use this booklet to document (1) the completion of all home visit assessments and the "tasks" for each home visit (as described in ***Sections II.B*** and ***II.C*** above) and (2) all attempted and completed contacts with the participant, including all attempts to schedule and complete home visit appointments (in Section C).

F. Post-Home Visit Activities

1. Compensation

There are a total of five assessments for ETS. The first two assessments (baseline and 6-week postpartum assessments) each include a telephone interview and two home visits. Participants are given $25 for completing each of these assessments. The third assessment (4-month postpartum assessment) includes a telephone interview only; participants are given $15 for completing this assessment. The last two assessments (6 and 12-month assessments) each include a telephone interview and two home visits; participants are given $25 for the 6-month assessment and $40 for the 12-month assessment. Therefore, participants can receive up to a total of $130.

Distribution of incentive payments may be given at the end of Home Visit B ONLY if the mother has already completed the telephone interview and all home visit activities. You will need to check the *Individual Activity Summary* report from the DMS to determine whether or not the telephone interview has been completed. Procedures for accessing this report (including an example of this report) are available in the ***DMS Manual of Operations.***

If the mother has completed the telephone interview, you may give her the incentive payment at the conclusion of Home Visit B. Women who receive any type of compensation must indicate their acceptance of these incentives by signing the *Incentive Receipt Form*. A copy of the *Incentive Receipt Form* is included at the end of this chapter. You should check the box corresponding to the activity as well as to the amount of compensation that you are giving the participant. Print the woman's name on the receipt, and ask her to sign and date it. You should also sign and date the form. Give a copy to the participant and file the original in her folder.

2. Documentation and Reporting

The *Home Visit Activity Booklet* is used to document all attempted and completed contacts with the participant (for the purpose of conducting the home visits) and the actual

completion of all home visit activities. Specifically, at the end of both Home Visit A and Home Visit B, you will need to document the following information in Section B of the Home Visit Activity Booklet for the appropriate time period (e.g., baseline, 6-weeks, etc.:

- the completion of each home visit activity (e.g., placement of nicotine monitors);
- scheduling information for the next home visit (e.g., date/time Home Visit B is scheduled or best times to call the mother for the next Home Visit A);
- any updated contact information (e.g., change in telephone number);
- the final result code for the visit, date completed, and home visitor's initials.

This information will then be entered into the DMS at the end of the day for both Home Visits A and B. Step by step instructions for entering data from the *Home Visit Activity Booklet* into the DMS are included in the ***DMS Manual of Operations***. Section C of the *Home Visit Activity Booklet* is used to document all telephone and in-person contact attempts; this information does not need to be entered into the DMS.

G. Consent Procedures

Current legislation related to many federally funded research projects requires that a potential participant be expressly informed of:

- the purposes of the study;
- the procedures that will be followed;
- any discomforts, risks, or benefits that might be associated with participation; and
- sources from which additional information about the study can be obtained.

This information must be made available to each participant either orally or in writing so that the individual can base her decision to participate or not to participate on full knowledge of the study and the consequences of involvement. The individual must also be informed that consent may be withdrawn and participation discontinued at any time. The purpose of this informed consent procedure is to protect persons from the possibility of injury, including physical, psychological, or social injury, as a consequence of participation in any research study. Failure of a recruiter to read or give an informed consent statement to a potential participant prior to an interview violates the individual's right to informed consent.

Project DC-STEP requires two stages of informed consent: (1) prior to taking the eligibility screening questionnaire on the Audio-Computer-Assisted Self Interviewing (ACASI) program, and (2) if eligible, prior to enrolling in the study. Copies of both the *ACASI Informed Consent Form* (ICF) and the *ETS-specific ICF* for both the main study and pilot test are included in ***Appendix A***. Both stages of informed consent will be completed by the Recruitment Specialist at the clinic when the participant is recruited to the study; therefore, as a Home Visitor, you will NOT need to do this during the home visit assessment.

However, because you will be conducting an observation of the home, which may appear somewhat intrusive to some participants, you will be required to obtain consent for conducting the home observation. A copy of the *Home Observation Consent Form* is included in ***Appendix***

A. This form must be read and reviewed by the participant at the beginning of EACH home visit assessment (i.e., the beginning of Home Visit A for the baseline, 6-week, and 4- and 6-month assessments). The *Home Observation Consent Form* explains the nature of the home visit observation, informs the mother that she may accompany you throughout the house during the observation, and asks if there is any room which she would not like to be observed. At the bottom of the form, either you or the participant can indicate which rooms the participant does not want included in the observation and both you and the mother must sign and date the form. The *Home Observation Consent Form* is printed on 2-part NCR paper, so you may give one copy to the participant and keep the original for the participant's folder at the clinic.

H. Confidentiality

All information obtained from and about a participant can and must be kept confidential. This means that the data about her cannot be associated with her as an individual. In fact, the Privacy Act of 1974 mandates that a breach of confidentiality during applicable data collection activities, such as the ETS Study, is a misdemeanor under federal law.

Project staff must maintain confidentiality of any and all information gathered from or about the eligible woman, whether it is information obtained from the clinic, from specific questions in an interview or intervention session, from casual observation during an interview, intervention session, home observation, etc., or from the abstraction of medical records. Guard against discussing a participant with a family member, friend, or any other person not connected with the study. Information about an individual woman, even without mentioning names, could possibly be repeated to someone who could identify her.

We ask that throughout the duration of the ETS Study, you maintain constant awareness that you have very personal and confidential information about the participating women. Treat all data collection forms as you would treat an official medical or social service record. Do not discuss individuals and/or their situations with anyone other than your supervisor or a member of the study team.

The following safeguards have been designed to ensure the confidentiality and protection of participant data:

- While the study is ongoing, all materials with identifying information will be kept in a secure place in the clinic. Study materials without identifiers should also be kept secure.
- The ACASI setting will be as private as possible and nobody will be able to see how the respondent answers the questions.
- Intervention sessions will be conducted in complete privacy.
- All telephone interviews and home visits will be conducted at a date and time that is convenient and secure for the participant.
- The participants' names will not be connected to any of their individual responses when data is analyzed.
- Data will be presented in aggregate so that individual responses cannot be identified.

The DMS will assign a subject identification number to each woman who appears at the clinic when her record is created in it. This identification is a unique number created to identify the participants in the study. Once assigned, the Subject ID replaces the participants' name on all data collected and analyzed. The identification number serves two purposes: it guarantees anonymity for the participant, and it allows the researchers to track the progress of the study and analyze the data. The following is the composition of the Subject ID:

- the first character, the letter "N," or "E" identifies whether the woman is an NRT (N) or ETS (E) Study participant;
- the second character identifies the laptop used for the A-CASI screening;
- the third, fourth, fifth, and sixth characters make a sequential number that identifies the woman; and
- the seventh character is a randomly assigned "check" digit.

Another way we will protect a woman's privacy during her participation in the study is by implementing the following procedure. At the time of enrollment, each woman will be asked to provide one or more telephone numbers where she can be reached by project staff. In addition, the woman will be asked, "If you are not available when we call, is it OK for our staff member to leave her name and a message that she called, or would leaving a message with someone else or on a machine cause you problems?" This information which will be entered into the DMS will be used by all project staff when attempting to contact the participant.

If the woman has no objection to project staff leaving telephone messages for her, we will identify ourselves in any messages as being from Project DC-STEP: Healthy Infants and Mothers Program. If questioned by the person answering the phone, staff will explain that the project is related to women's health issues. The project's focus on pregnancy and smoking will not be specified, nor will the woman be identified as a participant in a research study.

If a woman indicates that telephone messages should not be left, staff members will not identify themselves when another household member answers the phone. They will simply ask when the woman is expected to be available and say that they will call back at that time.

The widespread use of caller-ID may enable persons answering the phone to know the origin of the call; therefore in any situation staff may identify the site from which they are calling, without making reference to prenatal care. (That is, it should be O.K. to say they are calling from, for example, George Washington University Medical Center or Chartered Health.) Staff members should call only from project telephones. No calls will be made from staff members' home phones if safety is a concern.

I. Reporting Possible Child Abuse and Neglect and Other Adverse Events

The ETS Principal Investigator (PI) has obtained a *Certificate of Confidentiality* from the NIH that authorizes all project staff to maintain the confidentiality of all information shared by the women during the course of the study. With this Certificate, researchers cannot be forced to disclose information that may identify the participant, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (unless the information requested is necessary for the United States Government's auditing or evaluation of federally funded projects).

Nevertheless, if a study staff member has reasonable cause to suspect child abuse or neglect it must immediately be brought to the attention of Dr. Susan M. Blake, who will file a written report with Child Protective Services as per the laws in the District of Columbia. All participants are fully informed of this exception to confidentiality in the *ETS-specific ICF*. Specifically, in the *ETS ICF*, participants are informed that if there is any reason to suspect that the mother, baby, or someone else is in immediate danger, we will report such information to "the appropriate staff in the clinic and, if necessary, to the appropriate agency designated by law." Specific procedures for dealing with possible cases of child abuse or neglect are included in ***Appendix B***.

Additionally, recruitment, home visitors, interviewers, and intervention staff will maintain a heightened awareness for any other potential risks that could be attributable to study participation and will be encouraged to report such adverse events immediately to the study PI, Co-PI and their immediate supervisor.

1. Guidelines for Determining Adverse Events

As a general rule, if a participant experiences a "major medical problem" while in the study, it should be reported as an adverse event. Specifically, the following are considered adverse events (this list will be updated as additional adverse events are identified):

- Subject manifests suicidal ideation.
- Subject determined to be/have been psychotic.
- Subject suffers miscarriage.
- Subject suffers stillbirth.
- Subject suffers injury leading to Emergency Room visit, hospitalization, or death.
- Subject reveals/reports incident of child abuse.
- Subject under the age of 18 is enrolled.

The following are not considered adverse events:

- Subject experiences preterm labor.
- Subject experiences preterm birth.
- Subject gives birth to infant with low birth weight.
- Subject has an abortion.

Note that adverse events should be reported for women assigned to attention-control group as well as women assigned to ETS intervention. Adverse events reports should not be filed on persons who are not study participants (e.g. other family members). Further information regarding identification of other possible adverse events and emergency protocols for dealing with situations are included in ***Appendix B***.

If a staff member is unsure as to whether an event is an adverse event, he or she should consult with his or her supervisor or the study PI. **If in doubt, it is better to report an event that may be considered adverse than not.**

2. Reporting and Completing the Adverse Event Form

Upon learning of an adverse event, you must immediately inform your supervisor or the study PI, Dr. Susan Blake. Your supervisor or Dr. Blake will then determine if the event is reportable and, if so, will work with you to complete a *Report of Adverse Event Form*. A copy of this form is included at the end of this chapter. The *Report of Adverse Event Form* consists of three sections:

- Section A. Identification of Adverse Event
- Section B. Description of Adverse Event (Completed by Supervisor)
- Section C. RTI Use Only

The person learning of the adverse event should initiate the Report of Adverse Event Form by placing the appropriate Subject ID label in the upper-right corner of the form, or typing the ID onto the electronic copy of the form. This person will also record the date of the event and her name and title in Section A. The remainder of Section A and all of Section B are to be completed by the supervisor or study PI, with his or her input.

In Section B, the supervisor or study PI will describe the adverse event, how the event was learned of, and any action taken (by project staff and by others) at the time of the event. Dates and times may be provided, if known. The supervisor or study PI should next sign and date the Adverse Events Form on the appropriate lines in Section A. With this, Sections A and B should be complete.

3. Submitting the Form

After signing and dating the completed Report of Adverse Event Form, the supervisor or study PI should submit it within 24hrs by following these procedures:

1. Fax to RTI, ATTN: Jutta Thornberry, 301-230-4646
2. Email form to NICHD, Maurice Davis, for submission to the NICHD IRB.
3. cc Jutta Thornberry in email to Maurice Davis with form attached.
4. Mail hard copy to Jutta Thornberry, via first class mail.
5. Place the original form in the subject's file (at GW).

Note, a Report of Adverse Event Form should be completed and faxed to RTI within 24 hours of learning of an adverse event. Addendums are allowed, if necessary to report follow-up or additional action taken. If an addendum is made, it must be labeled with the appropriate Subject ID.

A summary of all Adverse Events will be submitted by Jutta Thornberry to the IRBs at NICHD, GW University, CNMC, and RTI on a quarterly basis, unless deemed "acute" by Dr. Susan Blake. If an event is deemed "acute," it will be forwarded immediately.

INSERT THE FOLLOWING FORMS:

Home Visit Activities Booklet

Incentive Receipt Form

Report Of Adverse Event Form